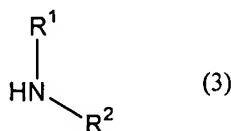


1. A process, which comprises contacting a carbazolone of formula (2),



(2)

formaldehyde or a formaldehyde precursor, and an amine of formula (3) or a salt thereof

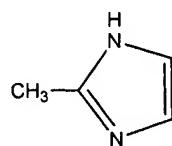


wherein R¹ and R² each independently represent a C₁ to C₄ alkyl group or together with the nitrogen atom they form a 5- or 6-membered ring, in a non-aqueous polar solvent and in the presence of a water binding agent to form a reaction mixture; and

reacting said carbazolone of formula (2) in said reaction mixture to form an intermediate-carbazolone reaction mixture.

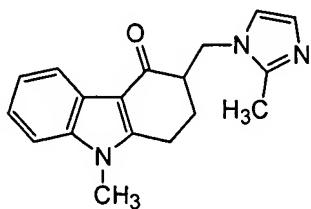
2. The process according to claim 1, wherein said formaldehyde precursor is paraformaldehyde.
3. The process according to claim 1, wherein said amine of formula (3) is selected from the group consisting of dimethylamine, diethylamine, piperidine, morpholine and the hydrochloride salts thereof.
4. The process according to claim 3, wherein said amine of formula (3) is dimethylamine hydrochloride.
5. The process according to claim 1, which further comprises providing an organic acid in said reaction mixture.

6. The process according to claim 5, wherein said organic acid is acetic acid.
7. The process according to claim 1, wherein said non-aqueous polar solvent is an amide, a ketone, an ester, an acid or a mixture thereof
8. The process according to claim 7, wherein said solvent is dimethylformamide.
9. The process according to claim 1, wherein said water binding agent is an organic or inorganic acid.
10. The process according to claim 9, wherein said water binding agent chemically bonds with water.
11. The process according to claim 1, wherein said water binding agent is acetic anhydride, methane sulfonic acid or phosphorus pentoxide anhydride.
12. The process according to claim 11, wherein said water binding agent is acetic anhydride.
13. The process according to claim 1, wherein not more than 10% of said carbazolone of formula (2) remains after two hours of reacting.
14. The process according to claim 12, wherein not more than 10% of said carbazolone of formula (2) remains after one hour of reacting.
15. The process according to claim 1, wherein said reacting step is carried out at a temperature within the range of 50°C to 150°C.
16. The process according to claim 1, which further comprises reacting in said intermediate-carbazolone reaction mixture an imidazole of formula (5)



(5)

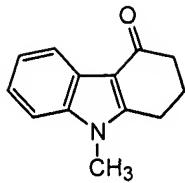
or a salt thereof to form a compound of formula (1)



(1)

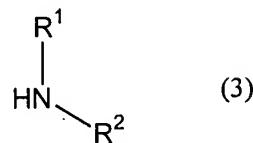
17. The process according to claim 16, wherein said imidazole compound of formula (5) is the hydrochloride salt thereof.
18. The process according to claim 16, wherein said imidazole compound is provided in said reaction mixture substantially simultaneously with the formation of said reaction mixture.
19. The process according to claim 16, wherein said imidazole compound is contacted with said intermediate-carbazolone reaction mixture 0.5 to 2 hours after said reacting of said carbazolone of formula (2) begins.
20. The process according to claim 19, wherein said imidazole compound is contacted with said intermediate-carbazolone reaction mixture after said reacting of said carbazolone of formula (2) is substantially complete.
21. The process according to claim 20, wherein said imidazole compound is contacted with said intermediate-carbazolone reaction mixture 0.5 to 1.5 hours after said reacting of said carbazolone of formula (2) begins.
22. The process according to claim 16, wherein said reaction of said imidazole compound of formula (5) is substantially complete within 8 hours from when it begins.

23. The process according to claim 22, wherein said reaction of said imidazole compound of formula (5) is substantially complete within 5 hours from when it begins.
24. The process according to claim 16, wherein said reaction of said imidazole compound of formula (5) is carried out substantially simultaneously with said reaction of said carbazolone of formula (2).
25. The process according to claim 16, wherein said reaction of said imidazole compound of formula (5) is carried out after said reaction of said carbazolone of formula (2) is substantially complete.
26. The process according to claim 16, wherein the total reaction time of said reaction of said carbazolone of formula (2) and said reaction of said imidazole of formula (5) is not more than 8 hours.
27. The process according to claim 26, wherein said total reaction time is not more than 7 hours.
28. The process according to claim 27, wherein said total reaction time is not more than 6 hours.
29. The process according to claim 16, wherein said reaction of said imidazole compound of formula (5) is carried out at one or more temperatures in the range of 90°C to 120°C.
30. The process according to claim 16, which further comprises converting said compound of formula (1) to a pharmaceutically acceptable salt thereof.
31. A process for making ondansetron, which comprises the following steps:
 - (a) combining in a non-aqueous polar solvent a carbazolone of formula (2);



(2)

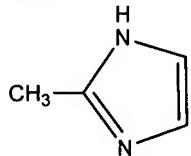
paraformaldehyde; an amine of formula (3) or a salt thereof;



wherein R¹ and R² each independently represent a C₁ to C₄ alkyl group or together with the nitrogen atom they form a 5- or 6-membered ring; a water binding agent; and an organic acid to form a reaction mixture;

(b) reacting said reaction mixture at a temperature from 50°C to 150°C until at least 50% of said carbazolone is converted to a reaction product; and

(c) subsequently reacting an imidazole of formula (5) in said reaction product-containing reaction mixture



(5)

or a salt thereof, to form ondansetron.

32. The process according to claim 31, wherein said reacting step (b) is carried out for not more than 1 hour and said reacting step (c) is carried out for not more than 5 hours.

33. The process according to claim 32, wherein said non-aqueous polar solvent is dimethylformamide, said water binding agent is acetic anhydride, and said organic acid is acetic acid.